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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,030	10/24/2003	Matthias H. Kraus	14014.0306U2	2346

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,030	KRAUS ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *October 6, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *35-59* is/are pending in the application.

4a) Of the above claim(s) *35-42 and 47-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *43-46 and 51-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The Election filed October 6, 2006 in response to the Office Action of September 6, 2006 is acknowledged and has been entered. Claim 43 has been amended and claims 51-59 have been added. Claims 35-59 are pending in the application and Claims 35-42, 47-50 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 43-46, 51-59 are currently under prosecution. It is noted that the species election requirement drawn to cancer-type is hereby withdrawn.

2. It is noted that the preliminary amendment filed in this case on October 24, 2003, but not referred to in the executed Declaration as originally filed, is not considered to be part of the original disclosure because the MPEP specifically states that "For applications filed on or after September 21, 2004 (the effective date of 37 CFR 1.115(a)(1)), a preliminary amendment that is present on the filing date of the application is part of the original disclosure of the application. For applications filed before September 21, 2004, a preliminary amendment that is present on the filing date of the application is part of the original disclosure of the application if the preliminary amendment was referred to in the first executed oath or declaration under 37 CFR 1.63 filed in the application. See MPEP § 602." Please review MPEP 714.01(e). However, a review of the Declaration does not reveal any reference to the preliminary amendment filed on October 24, 2003. The preliminary amendment is drawn to a method of classifying a cancer as being correlated with expression of an erbB-3 gene. However, the preliminary amendment as filed contains subject matter not otherwise included in the specification and drawings of the application since neither the term "classifying" nor the concept of classifying a cancer as being correlated with expression of an

erbB-3 gene is found in the specification as originally filed. It is further noted that if the amendment had been filed on any date other than the date that the application was filed, claims drawn to said subject matter would be rejected under the new matter provisions of 35 USC 112, first paragraph.

Since the preliminary amendment contains subject matter not otherwise included in the specification and drawings of the application as set forth above, Examiner is requiring applicant to provide a supplemental oath or declaration under 37 CFR 1.67 referring to such preliminary amendment. It is further noted that the failure to submit a supplemental oath or declaration under 37 CFR 1.67 referring to a preliminary amendment that contains subject matter not otherwise included in the specification or drawings of the application as filed removes safeguards that are implied in the oath or declaration requirements that the inventor review and understand the contents of the application, and acknowledges the duty to disclose to the Office all information known to be material to patentability as defined in 37 CFR 1.56. In response to this requirement, applicant must submit (1) an oath or declaration that refers to the preliminary amendment, (2) an amendment that cancels the subject matter not supported by the originally filed specification and drawings, or (3) a request for reconsideration. Please review MPEP 714.01(e).

Further, upon submission of the substitute oath or declaration, it is noted that the specification will be objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Because the claims as filed in the original specification are part of the disclosure, even though the material disclosed in the claims is not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. In re Benno, 768 F.2d 1340, 226 USPQ 683

(Fed. Cir. 1985). Thus amendment of the specification to include the material disclosed in the claims would obviate this objection.

Finally, it is further noted that, given that the preliminary amendment is drawn to subject matter not otherwise included in the specification and drawings of the application as set forth above, the instant application is not in fact a divisional application of the parent application, but rather a continuation-in-part of the parent application and the supplemental oath filed must include an acknowledgement of the duty to disclose to the Office all information known to be material to patentability as defined by 35 CFR 1.56.

3. In view of the preliminary amendment, Examiner has established a priority date of October 24, 2003 for the instantly claimed invention. If applicant disagrees with any rejection set forth in this office action based on examiner's establishment of a priority date October 24, 2003 for the instantly claimed invention, applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

4. Applicant's election with traverse of Group II, claims 43-50 drawn to the classification of a cancer as being correlated with expression of an erbB-3 gene is acknowledged. The traversal is on the ground(s) that the examination of the two groups will not involve an increased burden on the office because the methods of the two groups are nearly identical. The argument has been considered but has not been found persuasive because a review of the methods of the two groups reveals that the method of group 1 requires assay of a population suspected of having a cancer, wherein the cancer has not been diagnosed. On the other hand the population assayed in the method of Group II requires assay of a different population, that is the population having been diagnosed with cancer. Therefore,

the methods are drawn to methods which differ at least in objectives that is to diagnose cancer or to determine whether or not a cancer already diagnosied can be classified as being correlated with expression of an erbB-3 gene, differ in method steps (given that the starting materials from different populations are different), and differ criteria for success, that is the determination of diagnosis of cancer or classification of a cancer to be correlated with expression of erbB-3. Further, as to the question of burden of search, the literature search, particularly relevant in this art, is not coextensive and different searches and issues are involved in the examination of each group. Thus, contrary to Applicant's arguments, examination of the two groups involves an increased, undue burden on the office and although some method steps are identical, the two methods are not in fact identical.

Applicant also traverses the species elections required for marker to be assayed, Applicant argues that unity of invention exists where compounds included within a Markush group share a common utility and share a substantial feature essential to that utility and further argues that the species share a substantial structural feature as they contain the markers necessary to detect and classify cancer. The argument has been considered but has not been found persuasive because the species requirement is not drawn to a Markush Group given that the species of "protein" although contemplated in the specification was not claimed in the claims as restricted. Further, although Applicant argues that all three of the species share a substantial structural feature in that they are all detectable by the methods of the generic claims, this argument is not found persuasive because the feature detected in each of the species is not the same, one to the other. Applicant is reminded that upon allowance of the generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form

or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

As drawn to the election requirement drawn to sample species arising from a body fluid versus a tumor sample, Applicant argues that these samples also share the same utility as both are used to detect or classify a cancer. The argument has been considered but has not been found persuasive because Applicant's argument appears to be drawn to the restriction of the two groups, that is the diagnosis and classification groups and for the reasons set forth above, restriction of those groups is proper. Further, the two sample species have different structures and functions, are obtained by different methods and therefore represent samples obtained by and used in methods different one from the other and therefore are properly restricted. Applicant is reminded that upon allowance of the generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Specification

5. The specification on page 1 should be amended to reflect the status of the parent application serial number 09/170,699.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains,

or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 51-59 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of an antibody that binds to erbB-3 and not to EGFR or erbB-2 has no clear support in the specification and the claims as originally filed. It is noted that applicant does not point to support for the newly claimed limitations in the response filed with the amendment to the claims on October 6, 2006.

A review of the specification reveals support for "an erbB-3 antibody capable of binding or otherwise associating nonrandomly with an antigen of erbB-3 such that it does not cross react substantially with other-antigens. These antibodies specifically bind to an erbB-3 protein which includes the sequence of such polypeptide. In other words, these antibodies bind substantially only to erbB-3 receptor proteins and not to erbB (EGFR) or erbB-2 proteins.", see para 0031 of the published application. Further, the specification teaches at paragraph 0034 of the published application that "The antibody of this invention is exemplified by rabbit antisera containing antibodies which specifically bind to erbB-3 protein. Such receptor specific antisera are raised to synthetic peptides representing a unique portion of the erbB-3 amino acid sequence, having six or more amino acids in sequences which are sufficient to provide a binding site for an antibody specific for this portion of the erbB-3 polypeptide. Further, this unique portion of an erbB-3 amino acid sequence, of course, includes sequences not present in an erbB or an erbB-2 amino acid sequence, as predicted by the respective cDNA sequences. The erbB-3 specific anti-peptide antibody of the present invention is exemplified by an

anti-peptide antibody in polyclonal rabbit antiserum raised against any of the synthetic peptides given in SEQ ID NOS: 5-9, which are derived from the predicted sequence of the erbB-3 polypeptide. The specific detection of erbB-3 polypeptide with antiserum raised against the peptide given in SEQ ID NO: 5 is illustrated in mammalian cells transformed with an expression vector carrying a human erbB-3 cDNA (see FIG. 7). The antibody of this invention is further exemplified by erbB-3-specific monoclonal antibodies, such as the monoclonal antibody MAb E3-1, which was raised against the recombinantly expressed protein and is capable of detecting the native erbB-3 protein. MAb E3-1 specifically immunoprecipitated the mature 180 kDa erbB-3 protein from LTR-erbB-3 transfectants (FIG. 9A) and did not exhibit cross-reactivity with the EGFR or erbB-2 proteins." Thus, although the specification teaches antibodies that bind substantially only to erbB-3 receptor proteins and not to erbB (EGFR) or erbB-2 proteins, antibodies that are specific for erbB-3, the only recitation in the specification drawn to an antibody that binds to erbB-3 and not to erbB or erbB-2 is drawn specifically to MAb E3-1 and the limitation claimed, in the absence of the recitation of the Mab E3-1 broadens the scope of the scope of the invention as originally disclosed. It is noted that amendment of the claims, for example, to recite antiserum raised against SEQ ID NO:s 5-9 and/or Mab E3-1 will obviate this rejection.

8. Claims 43-46, 51-59 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43-46, 51-59 are indefinite because claims 43 recites the phrase "an increase in the level of expression" because the term "increase" is a relative term

which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is noted that although the specification does in fact define the phrase "greater amount" in the specification as originally filed, the specification does not define the term "increase". Amendment of the claim, for example to recite "greater amount" rather than "increase" would obviate this grounds of rejection.

Further, Claims 43-46, 51-59 are confusing because the preamble of claim 43 is not drawn to any particular level of erbB-3 gene and it does not appear that step (b) is in fact drawn to the claimed invention as recited in the preamble and the claim is not only confusing but unclear in the recitation of the additional step of comparing the level of expression of the erbB-3 gene to a control in order to classify a cancer as being correlated with increased expression of the erbB-3 gene.

Claims 43-46, 51-59 are indefinite in the recitation of the phrase classifying a cancer as being correlated with increased expression of "an" erbB-3 gene. The claims are indefinite in the use of the designation of "an" erbB-3 expression product as the sole means of identifying the claimed expression products. The use of laboratory designations only to identify a particular expression product renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct expression products. Although the specification defines a "gene product" when used in reference to erbB-3 encompasses the erbB-3 amino acid functional sequence as given in SEQ ID NO:4, the mature glycoprotein and these entities modified by other post translational modification, the term typically refers to the sequence as given in SEQ ID NO:4. However, the claims are not in fact drawn to **the** (emphasis added) erbB-3 gene

product consistently referred to in the specification, but rather are drawn to assaying "an" erbB-3 gene product, inferring that assay for gene products with sequences other than SEQ ID NO:4 are being claimed. Thus, the metes and bounds of claim protection cannot be determined, especially given the teaching in the specification, as drawn to the production of erbB-3 prolypeptide products, that these include those encoded by DNA sequences which encode polypeptide products having amino acid sequences which differ among individuals, that differ in at least one amino acid from the amino acid sequence of human erbB-3 but that have greater overall similarity to the amino acid sequence of human erbB-3 than to that of any other polypeptide (see page 8). Amendment of the claims, for example, to identify the erbB-3 gene product assayed as SEQ ID NO:4 would obviate the instant grounds of rejection.

Claim 43 and those claims dependent upon claim 43 are indefinite in that claim 43 does not provide a positive process step clearly relating back to the preamble of the claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 43-46, 51-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus et al, (PNAS, 1993, 90:2900-2904).

The claims are drawn to a method of classifying a cancer as being correlated with expression of an erbB-3 gene comprising measuring the level of expression of the erbB-3 gene in a sample from a subject diagnosed with cancer and comparing said level of expression in a sample from a control subject wherein an increase in the level of expression in the sample relative to the level of the expression from a control classifies the cancer as being correlated with increased expression of the erbB-3 gene, wherein the subject is a human subject, wherein the sample is a tumor sample, wherein the cancer is breast cancer, wherein the sample is contacted with an antibody that binds to erbB-3 and not to EGFR or ERBB-2, wherein the antibody is polyclonal or monoclonal, and binds to the extracellular domain of erbB-3, binds to the intracellular domain of erbB3, wherein the antibody is detectable, wherein the antibody is bound to a support.

Kraus, 1993 teach a method of classifying a cancer cell as correlated with expression of an erbB-3 gene product. The reference teaches that erbB family

members erbB and erbB2 have been implicated in malignancy and further teaches their critical role in the development of human neoplasia. Further, the authors disclose information drawn to the identification of the closely related erbB family member, erbB3 wherein the findings in cell lines raised the possibility that overexpression of this gene plays a role in some human epithelial malignancies (p. 2900, col 1). The reference further teaches the production of polyclonal antibodies against specific peptides from the intracellular domain of erbB3, wherein said polyclonal antibodies bind to the intracellular domain of erbB3 but not to erbB2 or erbB as well as production of monoclonal antibody that binds to the extracellular domain of erbB3 but not to erbB2 or erbB (para bridging pages 2900-2901, also column 2 on p. 2901 and col 1 on p. 2902). The authors teach that the availability of erbB-3 specific antibodies made it possible to explore expression and activity of erbB3 in human tumor cells (para bridging cols 1 and 2 on p. 2903). The authors indicate that the levels of erbB3 protein varied markedly among the breast cancer tumor lines analyzed, with a variability of 20-30 fold (p. 2903, col 2), and teach that the present findings strongly suggest that erbB3 protein is activated in some human breast tumors. Clearly indicating that the cancer cell line cells are classified as being correlated with expression of an erbB-3 gene product. The authors conclude that the present study demonstrates that overexpression of the erbB3 protein did not invariably correlate with its chronic activation in the cell lines tested and hence erbB3 activation may involve autocrine stimulation or subtle genetic alterations. In addition to breast tumors, expression of the erbB3 transcript has been observed in a wide range of human carcinomas including colon, lung, kidney, pancreas and skin. This prompts the search for evidence of erbB3 activation as an oncogene in these other common human tumors as well.

The reference teaches as set forth above but does not teach the assay of primary tumor cells from a subject that has cancer or its comparison to a normal control, does not teach that the antibody is detectable or bound to a solid support.

Dermer (Bio/Technology, 1994, 12:320) teaches that, petri dish cancer is a poor representation of malignancy, with characteristics profoundly different from the human disease Further, Dermer teaches that when a normal or malignant body cell adapts to immortal life in culture, it takes an evolutionary-type step that enables the new line to thrive in its artificial environment. This step transforms a cell from one that is stable and differentiated to one that is not, yet normal or malignant cells *in vivo* are not like that. The reference states that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature for more than 30 years.

Drexler et al (Leukemia and Lymphoma, 1993, 9:1-25) specifically teach, in the study of Hodgkin and Reed-Sternberg cancer cells in culture, that the acquisition or loss of certain properties during adaptation to culture systems cannot be excluded. Drexler et al further teach that only a few cell lines contain cells that resemble the in-vivo cancer cells have been (see attached abstract).

Zellner et al (Clin. Can. Res., 1998, 4:1797-1802) specifically teach that products are overexpressed in glioblastoma (GBM)-derived cell lines which are not overexpressed *in vivo*.

Hsu (in Tissue Culture Methods and Applications, Kruse and Patterson, Eds, 1973, Academic Press, NY, see abstract, p.764) specifically teaches that it is well known that cell cultures in vitro frequently change their chromosomal constitutions (see abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made a method of classifying a cancer as being correlated with expression of an erbB3 protein gene product in an assay of a tumor sample from a patient diagnosed with cancer because Kraus et al, 1993 specifically that members of the erbB family have been implicated in neoplastic processes and teaches the critical role for erbB and erbB2 in the development of human neoplasia as well as the identification of erbB3 wherein the overexpresion of the gene transcript in cell lines has raised the possibility that overexpression of erbB3 gene plays a role in some human epithelial malignancies. Further, the reference demonstrates that although the levels of erbB3 protein varied markedly among the breast tumor cell lines analyzed with a variability of 20-30 fold and that the overexpression of the erbB3 perotein did not invariably correlate with its chronic activation in the cell lines tested, that it appears that it is the activation of erbB3 protein that is associated with neoplastic processes based on the cell culture data. Given that the studies presented in the reference were drawn only to cell culture studies, given that the art recognizes, as taught by Dermer that cells in culture are not the same as those in primary tumors, given that Drexler et al, Zellner et al and Hsu et al specifically teach that cells in culture do not generally resemble in-vivo primary cancer cells, change their chromosomal constitutions, can not be predicted to express antigens at the same levels as those found in the in vivo condition, given that it is clear that characteristics of cultured cell lines generally differ significantly from the characteristics of a primary tumor, one would have been motivated to make an assay to classify breast cancer as being correlated with expression of an erbB3 protein product in order to be able to determine whether the information derived from the breast cancer cell lines was in

fact representative of breast cancer in vivo and to determine whether erbB3 is in fact expressed, is differentially expressed in a consistent manner and whether it is differentially activated in primary cancer cells compared with normal controls.. Further, given the express suggestion by Kraus et al to search for evidence of whether erbB3 activation is an oncogene in other tumors as well, one would have been motivated to assay primary tumor cancer cells from colon, lung, kidney, pancreas and skin for the same information. One would have had a reasonable expectation of success of successfully identifying erbB3 in assays of primary cancer cells because Kraus specifically teaches that the availablility of erbB3 specific antibodies made it possible to explore expression and activity of erbB3 in human tumor cells.

Although the reference does not teach the specific epitope required to produce monoclonal antibody to the extracellular domain of erbB3, given the information that such an epitope exists, that is that a single monoclonal antibody had been produced that is specific for erbB3 but does not bind to erbB and erbB2, it was well within the skill of the art to produce an antibody that was specific for erbB3 but does not bind to erbB or erbB2. Examiner takes note of the known homology of the erbB family members. Thus, one would have been motivated to produce the selective antibody given the known homology between the members in order to differentiate between expression of erbB3 and other family members. In addition, one would have been able, without undue experimentation to determine the epitope of said monoclonal antibodies and produce polyclonal antibodies toward that epitope specifically using the method of Kraus et al.

Further, although the reference does not teach making monoclonal antibodies to MK4 or MK5, whose polyclonal antibodies bind to the intracellular

domain of erbB3, it would have been prima facie obvious and one would have been motivated to produce hybridomas to the peptides taught in order to have a consistent supply of monoclonal antibodies to the epitopes within said peptides that would be useful to further characterize the protein using methods conventional in the art.

Finally, although the reference does not teach that the antibody is detectable, does not teach the antibody bound to a support, labeling antibodies for detection as well as binding antibodies to solid supports for immunodetection was conventional in the art at the time the invention was made. It is noted that the specification admits on the record at paragraph 0036 of the published application that methods of labeling antibody with a detectable moiety for the facilitation of detection of antibody/antigen complex or attachment of antibody to a solid support were known in the art at the time the invention was made.

10. No claims allowed.

11. If applicant disagrees with any rejection set forth in this office action based on examiner's establishment of a priority date October 24, 2003 for the instantly claimed invention, applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar, PhD
Primary Patent Examiner
May 29, 2007